CTR Collaborate Stakeholder Meeting Agenda

11 Sep 2024, 13:00 – 17:30 (CET/CEST)
Virtual meeting

CTCG, with the support of ACT EU Priority Action on Mapping and Governance, cordially invites all stakeholders to participate in a meeting to share information on the work completed by the participants of the different tracks within the CTR Collaborate project.

The CTR Collaborate project started in May 2023 with the aim to promote interaction between NCAs and ECs in EU/EEA implementing the Clinical Trials Regulation (CTR) and the Implementing Regulation (EU) 2022/20 on safety cooperation. The vision of the project is to i) promote health through novel therapeutic strategies with medicinal products, ii) have more clinical trials in the EU/EEA to facilitate research and provide new treatment options for patients ensuring that the rights, safety, and well-being of trial participants prevail over all other interests and iii) make the EU/EEA a more attractive location for conducting clinical trials.

To achieve these goals, the CTR Collaborate project focuses on several key objectives: i) it aims to ensure that clinical trials are safe and of high quality by maintaining high standards for CT applications and dossiers; ii) it aims to guarantee that assessments are conducted appropriately within legal timelines by harmonising procedures within and across Member States, while upholding ethical and regulatory standards; iii) the project aims to facilitate alignment between NCAs and ethics committees within and across Member States by building trust and a common understanding of CTR and endorsed guidance, ensuring effective collaboration across the EU/EEA.

CTR Collaborate Stakeholder Meeting Agenda

Chaired by Marianne Lunzer (AGES and CTCG chair) and Monique Al (CCMO and vice-chair CTCG)

11 Sep 2024, 13:00 – 17:30 (CET/CEST)

12:30 Joining and technical checks

13:00 Welcome and opening remarks

Opening remarks **10'**
Maria Lamas (Executive Director of the Spanish Agency for Medicines and Medical Devices, AEMPS)

13:10 Setting the scene

Setting the scene **20'**
Marianne Lunzer (CTCG chair)
Monique Al (CTCG vice-chair)

13:30 Session 1: Mapping of the EU landscape

Presentation & Q&A **25'**
Stefan Strasser (Austrian Medicines and Medical Devices Agency, AGES)

13:55 Session 2: Issue list (including CTIS) and proposals for solutions

Presentation & Q&A **45'**
Claire Bahans (Limoges University Hospital, FR (EC))
Elke Stahl (Federal Institute for Drugs and Medical Devices (BfArM), DE (NCA))
Ann Marie Janson Lang (Swedish Medical Products Agency, SE (NCA))
Jane Bryant (National Office for Research Ethics Committees, IE (EC))

14:40 Coffee break

14:50 Introduction to Breakout sessions

Introduction to Breakout sessions **10'**
Marianne Lunzer (CTCG chair)
Monique Al (CTCG vice-chair)

15:00 Session 3: Breakout sessions

Breakout session 1: Harmonization in the EU Clinical Trials Framework

Topic discussion **45'**

Wrap up and key messages **25'**

Breakout session 2: New strategies for streamlining clinical trial review and approval processes

Topic discussion **45'**

Wrap up and key messages **25'**

Breakout session 3: Fostering Innovation in Clinical Trials

Topic discussion **45'**

Wrap up and key messages **25'**

Breakout session 4: Enhancing CTIS Functionality and Operational Efficiency

Topic discussion **45'**

Wrap up and key messages **25'**

16:10 Coffee break & Return from Breakout sessions

16:25 Session 4: Reporting from the Breakout sessions

Chairs: Marianne Lunzer (CTCG chair) and Monique Al (CTCG vice-chair)

Presentation of key messages per session **60'**

17:25 Closing remarks

Wrap up **5'**
Marianne Lunzer (CTCG chair)
Monique Al (CTCG vice-chair)